510(k) SUMMARY of SAFETY and EFFECTIVENESS

I. GENERAL INFORMATION

Trade or (Proprietary) Name:	Prizm Medical, Inc. Micro-Z™ Stimulation System
Common or usual name:	Transcutaneous Electronic Nerve Stimulator (TENS)
Classification Name:	FDA has classified Transcutaneous Electronic Nerve Stimulator (TENS) as Class II devices. (21 C.F.R. § 882.5890)
Submitter's Name And Address:	Cathryn N. Cambria for Prizm Medical, Inc. Regulatory Resources Group 5536 Trowbridge Drive Dunwoody, GA 30338
Submission Date:	December 17, 2002
Legally Marketed Device To Which Claim Substantial Equivalence:	Empi Focus

II. INDICATIONS FOR USE

The Prizm Medical, Inc. Micro-Z™ Stimulation System is intended for the symptomatic relief and management of chronic (long-term) intractable (not easily controlled) pain and to help with the management of post surgical and post-traumatic acute pain problems.

The Prizm Medical, Inc. Micro-Z™ Stimulation System is also used for Neuromuscular Electrical Stimulation for the purposes of relaxation of muscle spasm, prevention or retardation of disuse muscle atrophy, muscle re-education, increase local blood circulation, maintain or increase range of motion, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. These uses were previously cleared under K951727.

III. DEVICE DESCRIPTION

Prizm Medical, Inc. Micro-Z™ Stimulation System is a compact battery operated transcutaneous electrical stimulator that delivers a micro-current to the surface area of our patented conductive Silver-Thera E.M. garment electrodes to provide electrical stimulation for chronic or intractable pain (see indications for use statement). It is designed not to exceed 100 volts across the garment electrodes. The technical Specifications for the Micro-Z™ Stimulator can be found in Appendix A. The stimulator is wearable with the Velcro® strip that attaches the device to the Velcro® arm/leg strap. It is microprocessor controlled, allowing for easy setup of the treatment parameters and precise control of each setting with a garment electrode dedicated to the upper or lower extremities. The system incorporates a proprietary connection from the stimulator to the electrodes that renders the device unusable without the dedicated electrodes. It is designed for ease of patient use with clearly marked patient intensity buttons.

Please refer to the Operations Manual (Exhibit A) for photographs and a more thorough description of the device.

The Prizm Medical, Inc. Micro-Z™ Stimulation System is intended for the symptomatic relief and management of chronic (long-term) intractable (not easily controlled) pain and to help with the management of post surgical and post-traumatic acute pain problems.

The primary function of the Micro-Z™ Stimulation System is the same as the Empi Focus and raises no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2003

Prizm Medical, Inc
c/o Ms. Cathryn N. Cambria
Regulatory Resources Group, Inc.
5536 Trowbridge Drive
Dunwoody, GA 30338

Re: K024181
Trade/Device Name: Micro-Z™ Stimulation System
Regulation Numbers: 21 CFR 890.5850, 21 CFR 882.5890
Regulation Names: Powered muscle stimulator, Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Codes: IPF, GZJ
Dated: March 26, 2003
Received: March 28, 2003

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

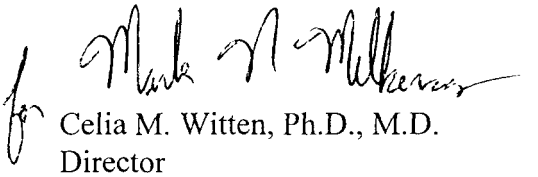
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K024181

Device Name: Prizm Medical, Inc. Micro-Z™ Stimulation System

Indications for Use:

The Prizm Medical, Inc. Micro-Z™ Stimulation System is intended for

1. Transcutaneous Electrical Nerve Stimulation for the symptomatic relief and management of chronic (long-term) intractable (not easily controlled) pain and to help with the management of post surgical and post-traumatic acute pain problems.
2. Neuromuscular Electrical Stimulation for the purposes of relaxation of muscle spasm, prevention or retardation of disuse muscle atrophy, muscle re-education, increase local blood circulation, maintain or increase range of motion, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
Use ____
(Per 21 CFR 801.109)

OR Over-The-Counter

for Mark N. Milhaus
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K024181